

Express Mail Label No. EL209599012US
U.S. National Phase Entry of PCT/GB00/01104
“Vaccine Composition”
Filed: 20 September 2001
PRELIMINARY AMENDMENT

Part A1

- C) cationic pluronics which are block copolymers or surfactants which are positively charged, in particular with NH₂⁺ groups
- D) complexing agents which form complexes with fatty acids such as deoxycholic acid, or
- E) cyclodextrins and their derivatives such as dimethyl β cyclodextrin.

Part A2

5. (Amended) A composition according to claim 1 wherein the carrier comprises a particle.

10. (Amended) A composition according to claim 7 wherein the microsphere comprises poly-(L-lactide).

11. (Amended) A composition according to claim 1 wherein the ratio of the chemical (ii) to the carrier is from 99:1 to 9:1 w/w.

12. (Amended) A composition according to claim 1 which is adapted for administration to a mucosal surface or is suitable for parenteral administration.

a3

15. (Amended) A method of protecting a mammal against infection, which method comprises administration of a composition according to claim 1 to a mammal.

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A4
20. (Amended) A microsphere according to claim 18 which further comprises
an agent that is capable of generating a protective immune response in an animal to which it
is administered.

A5
22. (Amended) A pharmaceutical composition comprising a microsphere
according to claim 19.

Respectfully submitted,



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Marked up version of claims showing changes made

3. (Amended) A composition according to claim 1 [or claim 2] wherein the said adjuvant chemical can act as an immunostimulant.

4. (Amended) A composition according to [any one of the preceding] claim[s] 1 wherein the said adjuvant chemical is selected from one or more of;

- A) poly-ornithine, for example of molecular weight from 5 to 150kDa;
- B) water soluble vitamins or vitamin derivatives such as vitamin E TPGS (d-alpha tocophenyl polyethylene glycol 1000 succinate),
- C) cationic pluronic which are block copolymers or surfactants which are positively charged, in particular with NH₂⁺ groups
- D) complexing agents which form complexes with fatty acids such as deoxycholic acid, or
- E) cyclodextrins and their derivatives such as dimethyl β cyclodextrin.

5. (Amended) A composition according to [any one of the preceding] claim[s] 1 wherein the carrier comprises a particle.

10. (Amended) A composition according to [any one of] claim[s] 7 [to 9] wherein the microsphere comprises poly-(L-lactide).

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11. (Amended) A composition according to [any one of the preceding] claim[s]
1 wherein the ratio of the chemical (ii) to the carrier is from 99:1 to 9:1 w/w.

12. (Amended) A composition according to [any one of the preceding] claim[s]
1 which is adapted for administration to a mucosal surface or is suitable for parenteral
administration.

15. (Amended) A method of protecting a mammal against infection, which
method comprises administration of a composition according to [any one of] claim[s] 1 [to
13] to a mammal.

20. (Amended) A microsphere according to claim 18 [or claim 19] which
further comprises an agent that is capable of generating a protective immune response in an
animal to which it is administered.

22. (Amended) A pharmaceutical composition comprising a microsphere
according to [any one of] claim[s] 19 [to 22].